DENTIAL

Report on Barclay

by

Lynn T. Kozlowski, Ph.D.
Scientist
Addiction Research Foundation

Associate Professor
Departments of Psychology and of
Preventive Medicine and Biostatistics
University of Toronto
Toronto, Ontario
Canada

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1.0 Orientation. I have been asked to give an opinion on whether the research concerning the Barclay issue raises 'serious question' about the appropriateness of standard FTC assays of this brand. I think that serious question does exist about Barclay and, further, I think that no additional research is needed to demonstrate that Barclay presents greater risks of high tar and nicotine yields to smokers than do other ultra-low-tar brands. Ironically, the studies that are most conclusive on this point are the B&W Gori-Darby Studies: This research shows that Barclay, as used by consumers, delivers higher levels of nicotine than do other, ostensibly comparable, low-tar brands. Other studies are less conclusive, but, nonetheless, they agree in their main findings that Barclay is inappropriately assayed by the FTC method. This report is intended to provide a brief review of the studies that either (a) cause doubts about Barclay or (b) reduce doubts about Barclay.

1.1 As was pointed out by B&W, PM and Lorillard, the air-dilution systems on all ventilated-filter cigarettes can be defeated behaviorally, by means of the smokers' placement of lips or fingers. All ventilated filter cigarettes can have their air-entry holes blocked. Barclay, in addition, can have its air channels blocked (holding the filter between the teeth can certainly provide the necessary pressure)* and, further, can have its air-exit holes blocked. Barclay does appear to pose added risks of

* I think that lip pressure can cause the channels to buckle; place a Barclay carefully in your mouth and squeeze: You can 'hear-feel' the channels buckling.

hole-blocking. The magnitude of these added risks remains to be determined.

1.2 The FTC cigarette testing procedure is designed to give estimates of the delivery of tar and nicotine (and carbon monoxide) to an idealized 'average' smoker, to provide some objective basis for ranking the yields of cigarettes. The basic question of 'delivery' (or of tar and nicotine yield) refers to the amount of these toxic products reaching the mouth of the smoker. Once the smoke reaches the mouth, its fate depends on many factors that are all subject to substantial individual variation (e.g., depth of inhalation, duration of inhalation, microsomal enzymes in the liver, urinary pH, exercise).

1.3 Studies that depend on measures of nicotine can be considered approximate measures of delivery. Research by Hill & Marquardt (see appendix) indicates that fairly large differences (certainly greater than 0.1 mg) in standard FTC yields of nicotine are required, before substantial differences in cotinine levels will be found. More will be said on the Gori-Cotinine Studies in a later section of this report.

2.0 The Panel Studies - Sensory Profiles. I do not believe that any of these studies should be weighted very heavily in the FTC's decision. Even if studies on other cigarettes have shown a high correlation between perceptual judgements and tar, Barclay may violate this relationship and still be producing acceptable FTC tar estimates.

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In other words, if Barclay had genuinely succeeded in modifying the 'taste'— tar relationship, then, one would expect to find a 1 mg tar cigarette that tasted like a stronger cigarette.

3.0 The "Butt" Studies. A butt-nicotine study on ventilated-filter cigarettes is inadequate, if it does not allow for changes in filter-efficiency due to changes in puff-velocity and air-dilution. Therefore, the B&W studies do not provide acceptable scientific evidence on the actual delivery of Barclay or its delivery relative to other ultra-low-tar brands.

3.1 Though from a laboratory-analytical viewpoint, the PM studies are first-rate, the exact procedure seems to me to be biased against Barclay and for Cambridge. The on-line dilution measurement device provides a good measure of dilution on machine-smoked cigarettes, but it provides a limited measure of human smoking behavior.

3.2 Fact. On the one hand, the device protects the air-entry holes (e.g., on Cambridge) from being blocked with fingers or lips. Such behavioral blocking (if it occurred) would show that Barclay's competitors were also susceptible to producing a divergence between human-smoked and machine-smoked tar yields. This biases toward finding Barclay worse than the others, when in fact, Barclay and the other ultra-low tars might be alike (for the same basic reason) in commonly delivering more tar than the FTC ratings indicate. All air-dilution filters compared to non-ventilated filters may pose a risk to the integrity of the relative ranking of tar yields throughout the entire tar scale.

3.3 Opinion. On the other hand, the on-line device may bias toward the lip draping effect. The distance between the air-entry holes and the end of the cigarette on Barclay is only 12-13 mm. The placement of the device reduces this distance by at least 1 mm. Subjects would be likely to wish to avoid touching or disturbing the apparatus with their lips, so they might place the cigarette less far into their mouths. Clearly not all smokers hold cigarettes in their mouths so that their lips drape over the edge of the end of the filter. (Recently, Winston ads, e.g., show smokers holding cigarettes between their teeth; in my Lab, I have seen lipstick stains that only cover air-entry holes and are well away from the end of the cigarette.)

3.4 The August 31, 1981 PM submission does indicate that the available length of the filter in the PM apparatus does not affect the dilution change caused by human smoking. Unfortunately, this report does not resolve the question of lip-draping or channel collapse. This study does support the PM claim that human smoking does reduce air-dilution on Barclay and increases tar-yield. (It should be noted that the B&W concerns about the subject population are legitimate.)

3.5 The finding that the other ultra-low-tar brands do not diverge from their FTC yields when smoked by people may be pre-determined in that their ventilation systems are protected by the measuring apparatus from possible behavioral interventions that would be functionally equivalent to the blocking of the

air-exit holes on Barclay. Kozlowski et al. (Brit. J. of Addictions, in press, see Appendix) demonstrate that behavioral hole-blocking does occur in more conventional ventilated-filter cigarettes. (Compare the statements on p.42 of the October 23 submission). Note that no assertion is being made here other than some low-tar smokers do block ventilation holes.

3.6 Despite the 'artificiality' of the measurement apparatus, I think that the results do indicate that the air-dilution of Barclay does change when smoked by humans. The assumptions that PM makes about the 'butts' are reasonable and likely to be correct, but as B&W points out, air-dilution is not the only factor that can influence filter efficiency. A sample of consumers should be used in these studies.

4.0 Subject Populations. It is difficult to judge how much the subjects (employed by the tobacco companies) know of the role of air-dilution in reduced-yield cigarettes, but it is probably fair to assume that these smokers are more aware about cigarette technology that would be the general public. These subjects may be more inclined to avoid ventilation holes (e.g., on Cambridge, Now, Carleton) because they understand the implications of hole-blocking.

4.1 There is no question that behavioral defeat of dilution filters is within the competence of almost any smoker; however, it is not clear just what percentage of naive smokers regularly block ventilation holes (entry or exit holes).

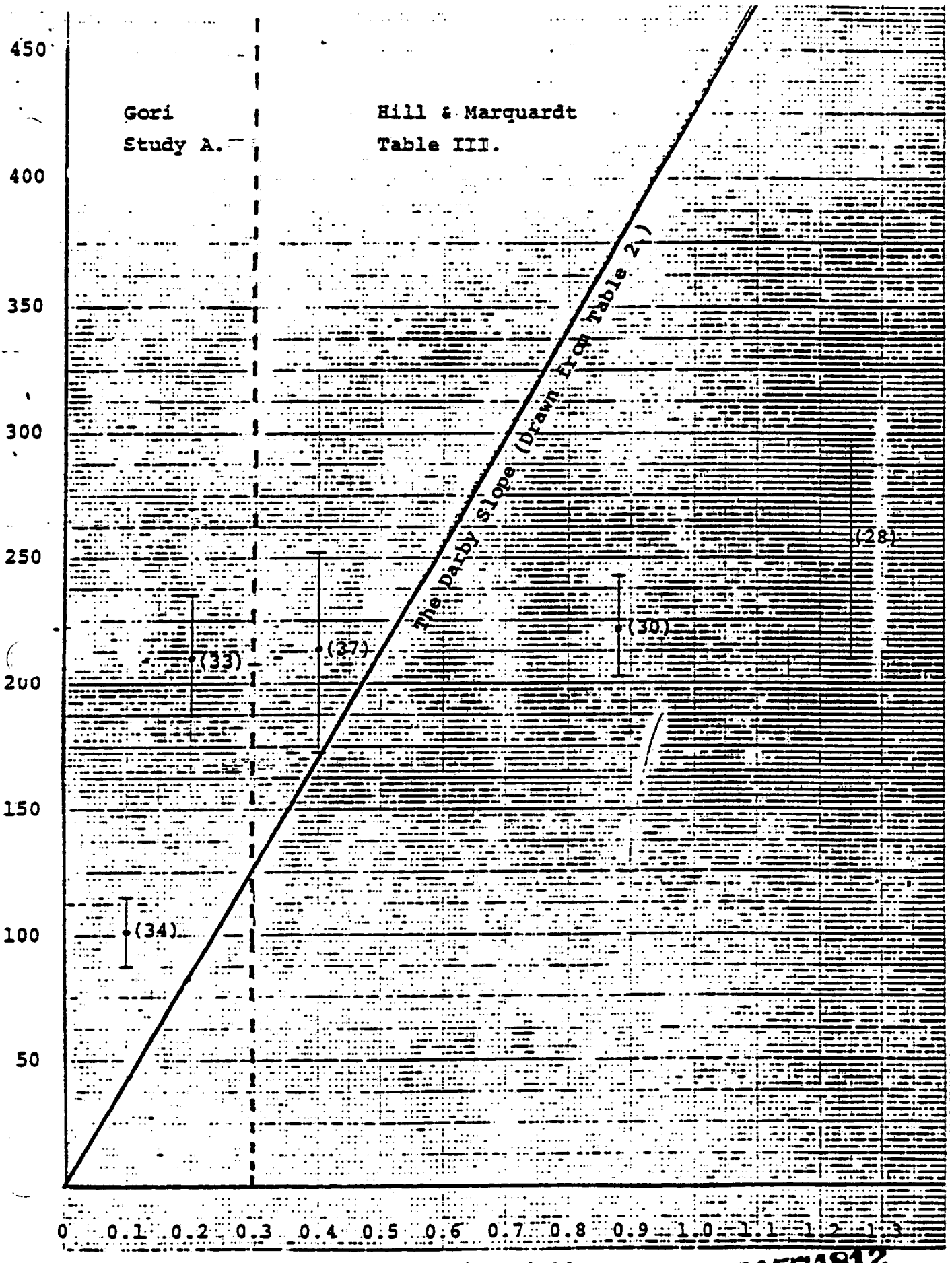
4.2 The FTC should be most interested in the yields to a regular smoker of a given brand, because this individual will be most affected by the misleading information. Studies on hole-blocking should employ smokers who have adopted the brand in question as their usual brand. Hole-blockers will be more likely to stick with an ultra-low-tar brand, because these cigarettes will be higher-yielding and more satisfying. Those who try the ultra-low tar brands, but who do not learn some form of hole-blocking, could be expected to show a higher rate of dissatisfaction with the brand. Consequently, the probability of encountering hole-blocking with a particular brand should be higher in a sample of long-term ultra-low tar smokers, than in a sample of smokers who are novice smokers of these cigarettes.

5.0 The Lorillard - Uninhaled Puff Study. This study suffers from the problems expressed in Section 4. None of the smokers were regular smokers of ultra-low-tar brands. They may know 'too much' about the function of vent-holes. Nevertheless, these results do indicate that the tar delivery of Barclay is higher than the FTC ratings suggest. Unfortunately, these results are not persuasive that other ultra-low-tar brands are not guilty of the same problem. The B&W objections to this study (cited on p.25, October 23) have almost no merit. Their own consultant (Gori) has emphasized the need for 'within subject' (repeated measure) comparisons: B&W Figure 1 presents the 'between subject' comparisons from the Lorillard study.

6.0 Cotinine Research. Although cotinine is too far downstream from nicotine delivery to be an ideal measure of the nicotine yield of cigarettes, within-subject designs, using many repeated measures, can make cotinine an acceptable marker of nicotine intake.

6.1 The Gori-Darby Studies. Taking the findings at face value, it is not possible to judge whether these results show that Barclay is more like Cambridge and Carlton than it is like higher-yield brands. Crucial higher-yield comparisons are not made. One cannot evaluate the shape of a mathematical function by comparing only 2 points (here 0.1 mg and 0.2 mg nicotine). Although Gori raises some legitimate concerns about comparing higher-yield cigarettes to lower-yield cigarettes, the fundamental question (i.e., where does Barclay stand in relation to other brands—higher and lower) requires that at least one higher-yield cigarette be evaluated for its cotinine 'yield'. It should be noted that none of Gori's misgivings about doing higher-yield comparisons can be applied to comparisons to 0.3 or 0.4 mg nicotine cigarettes.

6.2 It is ironic that B&W would complain about the "complex formulas and abstruse statistical manipulation" of PM's butt study, and at the same time rely on the complex formulas and abstruse statistical manipulations of Dr. Darby's study. I do not think that the simulation contributes anything beyond Dr. Gori's study. Until a fuller range of nicotine yield-cotinine



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level comparisons are available, Dr. Darby's first approximation will remain largely untested.

6.3 I have prepared Figure 1 to illustrate why the interpretation of these findings (again, if taken at face value) is not at all clear. Rather than simply using arbitrary figures, I have used the results of a well-known study (although un-cited in the submissions by Gori or Darby) by Hill and Marquardt (Clinical Pharmacology and Therapeutics, May 1980, 652-658, see Appendix). Figure 1 shows the relationship between nicotine yield and cotinine levels in two studies. To the left of the dotted line is the Gori Study A; to the right of the dotted line is the Hill & Marquardt Study. (Gori Study A is used because Darby supplies the 'raw' data from it in his report and because the Darby Study depends upon Study A.) There is no way of knowing how comparable the 3 subjects from Hill & Marquardt are to the 12 subjects from the Gori Study. The Darby slope is drawn from his Table 2, rows 1 and 4: attend to the slope rather than the intercept of this line. The numbers in parenthesis are the number of cigarettes smoked per day. Cotinine values are means ± SEM.

6.4 If we assume <u>for purposes of illustration</u> that the dotted line dividing the two experiments does not exist and that each mean cotinine level is made up of measures from the same subjects, this pattern of results would suggest that Barclay is more like higher-yield cigarettes than like the 0.1 mg nicotine cigarettes. Perhaps higher-yield comparisons would show that Barclay is more like the other ultra-low tars than like the

0.4 mg or the 1.25 mg nicotine cigarettes, but until the research is done, one (including Dr. Darby) can do little more than guess about the outcome. From a comparison of the Darby slope with the results of Hill & Marquardt, it looks as if the proposed model may be very inaccurate at higher nicotine-yield levels.

6.5 So far, I have argued that the Gori studies are inconclusive.

I think that other lines of reasoning indicate that the Gori studies provide solid evidence against the B&W position. There is no valid reason to expect that a 0.1 mg and a 0.2 mg nicotine cigarette would produce reliably different cotinine levels in smokers. Measurements can be hyper-precise, i.e., too precise for the uses to which they are put. This 0.1 mg nicotine differential is too small to be behaviorally consequential. (Consider an analogy: if EPA mileage estimates showed one car to deliver 25.2 (or 25) mpg and another car to deliver 25.7 (or 26) mpg in their laboratory tests, would you expect that these cars in the hands of 40 drivers would show a significant difference in average mpg achieved?) Dr. S. Green, a researcher from the British-American Tobacco Company has written an interesting report "Ranking cigarette brands on smoke deliveries". Dr. Green concludes that "small differences in simple tables [of tar/nicotine deliveries] are meaningless" (p388)(see Appendix).

6.8 For anyone aware of the variability of human smoking behavior (cf. p42 of the October 23 submission), it should be apparent that a difference between a 0.1 mg and a 0.2 mg cigarette would be very difficult to measure outside of the smoking-machine laboratory. (See the discussion by Kozlowski, Addictive Behaviors,

p214, in Appendix, on how variability in human smoking can make it difficult to detect a difference in actual yields to smokers, unless large differences in FTC yield are at issue).

6.9 There is no reason to doubt the appropriateness of the most recent FTC ratings of Cambridge, Carlton, and Barclay: these figures show, in agreement with Gori and B&W, cigarettes that yield 0.1, 0.1 and 0.2 mg nicotine, respectively (see Table 1). If one considers the FTC results to the second decimal place and considers the variance of these scores, an interesting fact emerges. Though these scores can be rounded to give yields that differ by 0.10 units, in fact, 0.11 mg cigarettes (Cambridge and Carlton) and 0.15 mg nicotine cigarettes (Barclay) differ by only 0.04 mg. (Darby, then, was actually dealing with an FTC yield difference that he over-estimated by 60%.) This difference is not statistically reliable (t (38) = 1.2, $p > .30$). This means that the FTC smoking machines did not distinguish between these '0.1' and '0.2' brands at an accepted level of statistical significance. A perusal of Table 1 should also confirm that the smoking machines do not reliably distinguish the brands in question: Note that, to Lorillard, Carlton and Barclay both deliver '0.2' mg of nicotine and that, to PM, Cambridge and Carlton both deliver '0.2' mg of nicotine. Table 1 also shows that the 'rounding error' can be a serious problem when dealing with these small doses. If smoking-machines have difficulty evaluating this miniscule difference in nicotine yield (in an environment that is temperature and humidity controlled), how can smokers have

so little difficulty in distinguishing these cigarettes? Of course, smokers could not be expected to show a difference that the machines have such difficulty in showing: When smoking Barclay, the smokers must have been getting substantially more nicotine from this brand than from the other ultra-low-tar brands.

7.0 In other words, Gori has shown that brands that do not differ significantly in nicotine yields on smoking-machines, do differ significantly in cotinine levels in smokers. The obvious explanation for this finding is that Barclay delivers much more nicotine than do the other nominally ultra-low-tar brands. Barclay stands alone among these ultra-low yield cigarettes. It delivers more cotinine than do Cambridge, Carlton and NOW 0.1 mg cigarettes).

7.1 To summarize, I think that Barclay is not properly assayed by the FTC method and that it delivers tar and nicotine to smokers out of proportion to its ranking on the FTC lists. It should be noted that all ventilated filter cigarettes (see paragraph 1.1) are subject to a similar violation of the integrity of the rankings, but that Barclay (as supported by the PM air-dilution studies, the Lorillard Uninhaled-Puff Study, and the above analysis of the Gori Studies) is significantly more prone to this violation than are conventional ventilated-filter cigarettes.

8.0 Consumers should be warned about the special risks of using ventilated-filter cigarettes (including Barclay) and about the higher risks of the Barclay-type filter.

TABLE 1

BRAND	LAB	FTC TAR EXACT	FTC TAR ROUNDED	FTC NICOTINE EXACT	FTC NICOTINE ROUNDED	PUFF COUNT
Barclay	RJR	1.6	2	0.17	0.2	8.5
	PM	2.1	2	0.28	0.3	8.0
	LOR	0.9	1	0.20	0.2	—
	FTC			0.15 (±0.03) *	0.2	
Cambridge	RJR	0.6	1	0.11	0.1	7.6
	PM	1.3	1	0.17	0.2	7.0
	LOR	—	—	—	—	—
	FTC			0.11 (±.01)	0.01	
Carlton	RJR	0.6	1	0.11	0.1	6.8
	PM	0.9	1	0.18	0.2	7.4
	LOR	0.5	1	0.15	0.2	—
	FTC			0.11 (±.01)	.01	
NOW	RJR	2.5	3.0	0.23	0.2	7.2
	PM	—	—	—	—	—
	LOR	0.9	1.0	0.18	0.2	—
	FTC	—	—	0.22 (±.01)	0.2	—

* Twice Variance

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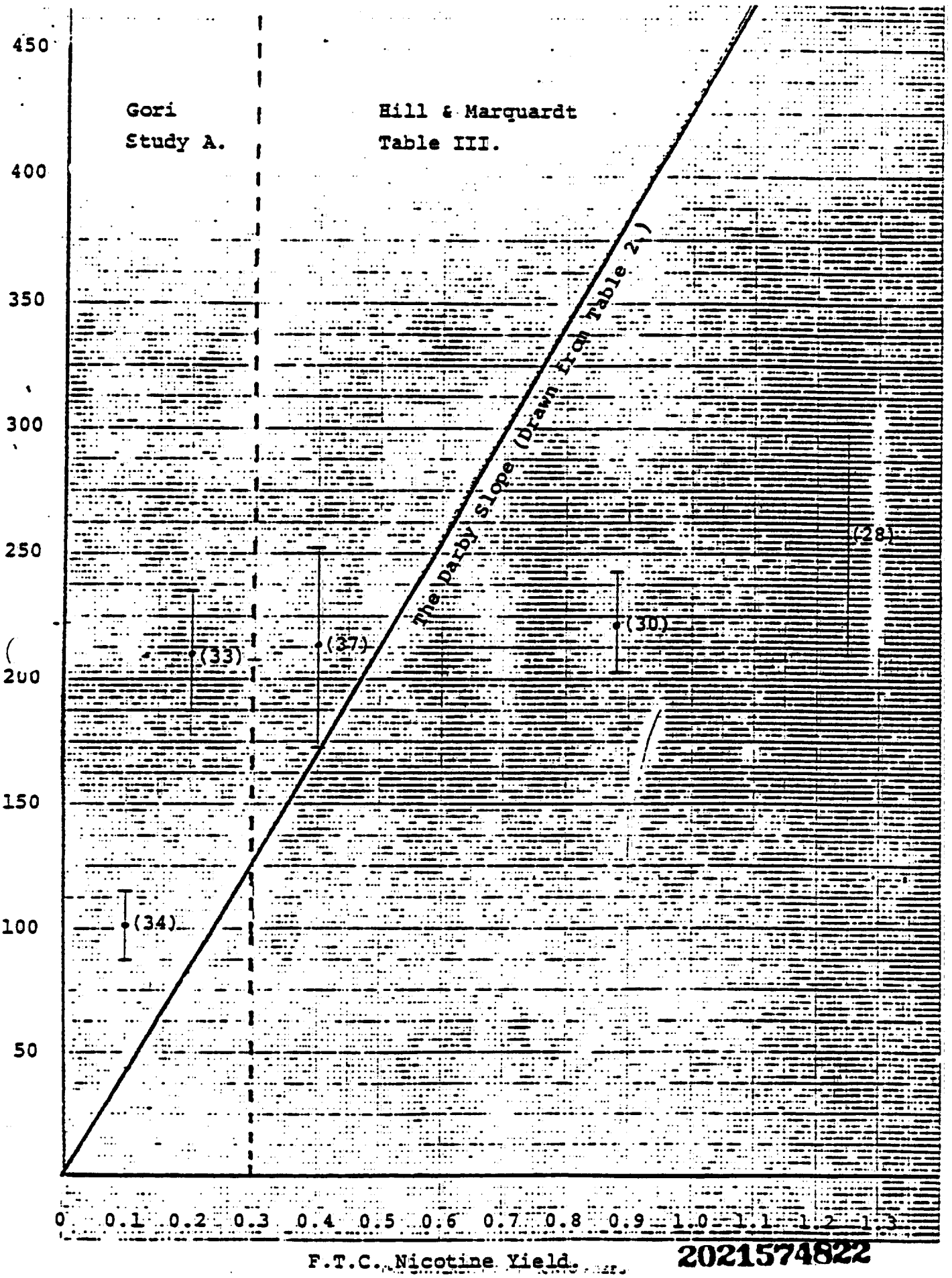

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